Not Reported in F.Supp.2d, 1999 WL 509471 (S.D.N.Y.), 1999-2 Trade Cases P 72,603
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distinguished experts, all of whom, however, are directly associated with the MORE study and have an interest in demonstrating its scientific significance: Dr. Marc Lippman, head of the Lombardi Cancer Center at Georgetown University, Dr. Steven Cummings, Professor of Epidemiology and Biostatistics at the University of California, San Francisco, and Dr. Steven Eckert, an Eli Lilly statistician. Their testimony supports the promising nature of the MORE data with respect to breast cancer risk reduction. However, their testimony is insufficient to persuade the Court that Evista has been proven to reduce the risk of breast cancer.

99. Dr. Lippman is a distinguished oncologist who is a member of Eli Lilly's Oncology Advisory Board, a member of the breast cancer adjudication committee for the MORE study, and a coauthor of the recently published JAMA article concerning raloxifene and breast cancer. Lippman Dep. Tr. at 13, 51-52, 54-56; Tr. at 1106-07 (Dere).

100. Dr. Lippman opined only that a median of 40 months of treatment with raloxifene reduces the risk of newly diagnosed breast cancer in postmenopausal women with osteoporosis-a much narrower statement than the blanket risk reduction claim that has been made by Eli Lilly sales representatives and that Zeneca seeks to enjoin. Dr. Lippman conceded that, based on the existing data and given the patient population in the MORE study, one cannot draw the same conclusion with respect to the female population at large. Lippman Dep. Tr. at 74, 76-79. Notably, this testimony was confirmed by Eli Lilly's Dr. Will Dere, who acknowledged that the statement "Evista offers proven reduction of breast cancer" without any qualifiers "would not be right as a single sentence for Eli Lilly to state that."Tr. at 1108-09 (Dere). Dr. Dere also agreed that it would be an "overstatement" to say that Evista decreases breast cancer by 70 percent, without any qualifiers. Tr. at 1109-10 (Dere).

101. Dr. Lippman also candidly acknowledged that although he is convinced that the MORE data is accurate and proves to a reasonable degree of medical certainty that raloxifene reduces the risk of breast cancer among postmenopausal osteoporotic women, other physicians could look at the data from the MORE study and conclude that the data are not sufficient to prove that raloxifene reduces the risk of breast cancer. Lippman Dep. Tr. at 62-63, 168-72. As Dr. Lippman explained:

I believe that it is perfectly appropriate, as happens every single day in the verification of new agents, that some physicians become convinced of something before others do.... I think that right-minded physicians based on data can come to conclusions at a different rate. And I would not-this is important to me. I would not dispute that another physician could look at these data and say they are interesting, but I am not persuaded yet. I would not myself change my practice. I think that's absolutely the way medicine changes over time.

***29** Lippman Dep. Tr. at 62-63.

102. Dr. Cummings is the primary investigator for the MORE trial, as well as a member of Eli Lilly's Raloxifene Advisory Board. Tr. at 598, 682-84, 690-92 (Cummings).

103. Dr. Cummings opined that raloxifene reduces the incidence of breast cancer only in postmenopausal women, a narrower claim than that at issue here. Tr. at 712-13. Dr. Cummings' testimony also indicated that the participants in the MORE study may have been at lower risk for breast cancer than the participants in the BCPT trial based on the relative bone density of the two groups. Tr. at 720-21, 739 (Cummings).

104. While Dr. Cummings was plainly convinced of the significance of the results of the MORE study as it relates to the reduction of the risk of breast cancer , he is interested in that conclusion and his views are not shared by the FDA or other disinterested organizations.

105. Eli Lilly also relied on the testimony of Dr. Stephen Eckert, a senior Eli Lilly statistician, who opined that Evista"has clearly been statistically proven in the MORE trial to reduce the incidence of breast cancer."Tr. at 932 (Eckert). He agreed, however, that, given the small number of breast cancer events in the study, a small shift in the number of cases would have an enormous impact on the p value and could undercut the statistical significance of the interim results. Tr. at 975-76 (Eckert).

3. *The JAMA article*

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106. Finally, Eli Lilly relies heavily on the fact that a peer-reviewed article concerning the MORE study breast cancer results was published in the June 16, 1999 issue of JAMA. The JAMA article, which is co-authored by Drs. Cummings, Eckert, and Lippman, among others, sets forth the authors' narrow conclusion that "a median of 40 months of treatment with raloxifene decreases the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer."Tr. at 712 (Cummings); Def.'s Exh. L-9 at 2196. Again, this is a narrower claim than the blanket statement being made by Eli Lilly sales representatives.

107. The article does not state that raloxifene has been or even may be proven to reduce the risk of breast cancer in any other segment of the female population. Nor does it definitively conclude that Evista has been proven to reduce the risk of breast cancer in the population that was tested. To the contrary, the authors concede that there is no data that confirms whether the existing results will continue to be seen and that "the MORE trial is continuing to assess the effectiveness and safety of longer term use of raloxifene" in postmenopausal osteoporotic women. Def.'s Exh. L-9 at 2196; Tr. at 664 (Cummings); Lippman Dep. Tr. at 66-67, 75.

108. Given Eli Lilly's reliance on this publication, there was extensive testimony about the significance of the peer review process and whether that process, in and of itself, signifies some form of scientific " proof." It is plain that it does not. Both parties' experts explained that peer reviewers as a rule are given only the manuscript of the article and nothing else. Eli Lilly's own experts conceded that this was true in the case of the JAMA article. Tr. at 393-94 (Carlson); Tr. at 765 (Cummings); Lippman Dep. Tr. at 79-81.

***30** 109. The peer reviewers at JAMA were not given the MORE protocol and thus were not in a position to assess the flaws in the MORE study design as a breast cancer trial. Nor were they given the results of the nine other Evista trials which failed to demonstrate that Evista reduces the risk of breast cancer. Finally, the peer reviewers were not given the FDA's comments concerning the inadequacies of the MORE results. Tr. at 765-66 (Cummings); Tr. at 990-91 (Eckert).

110. In any event, the mere fact of publication of a peer-reviewed article does not prove that the claim in question is true. Indeed, the FDA has stated that " [t]here are ... reasons to be skeptical of the conclusions of published reports of studies. Experience has shown that such study reports do not always contain a complete, or entirely accurate, representation of study plans, conduct and outcomes. ... [I]ncompleteness, lack of clarity, unmentioned deviation from prospectively planned analyses, or an inadequate description of how critical endpoint judgments or assessments were made are common flaws. Typically, journal article peer reviewers only have access to a limited data set and analyses, do not see the original protocol and amendments, may not know what happened to study subjects that investigators determined to be non-evaluable, and thus may lack sufficient information to detect critical omissions and problems."*Guidance for Industry* at 17.

111. In sum, though the MORE data are promising and may in the future be proven to measure accurately the efficacy of raloxifene in reducing the incidence of breast cancer in some segment of the population, Evista has not yet been proven to reduce the risk of breast cancer. Based on all of the evidence, the two claims that Eli Lilly has been making for Evista-that it has been established that Evista reduces the risk of breast cancer and that Evista has been proven comparable or superior to tamoxifen for reduction of the risk of breast cancer-are literally false.

G. The harm to Zeneca, Barr, and the public

112. Zeneca's witnesses testified to the substantial negative impact of Eli Lilly's actions on Zeneca. Ms. Anson testified credibly that "Zeneca has invested an enormous amount in tamoxifen over the last 20 years in research and development," and that this investment has been jeopardized by Eli Lilly, as has Zeneca's reputation and goodwill with physicians. Tr. at 68 (Anson). Ms. Anson also highlighted the fact that because the breast cancer prevention market is just now being created by Zeneca, Eli Lilly's actions have had a pernicious effect on Zeneca's launch and the marketplace itself, if not immediately then as a long term matter. Tr. at

100 (Anson). These are, according to the uncontradicted testimony of Ms. Anson, damages that Zeneca cannot quantify. Tr. at 70 (Anson).

113. Market research conducted by Reed/Haldy/McIntosh, a reputable market research firm in the prescription drug field, likewise highlighted the effect of Eli Lilly's actions on Zeneca and Barr, the only two distributors of tamoxifen. The survey concluded that of the physicians surveyed 11 percent of their prescriptions for Evista are being written primarily for breast cancer prevention, as opposed to either for osteoporosis or for osteoporosis plus breast cancer, and that 35 percent of physicians have written at least some of their Evista prescriptions for the primary purpose of breast cancer prevention. Pl.'s Exh. 72 (NolvadexBreast Cancer Prevention: Awareness, Trial and Usage Study by Reed/Haldy/McIntosh & Assocs. dated Feb. 15, 1999) at 31, 32; Pl.'s Exh. 80; Tr. at 477-79, 487-89 (McIntosh). This study does not, however, indicate that these prescribing patterns of physicians are the result of statement made by Eli Lilly, although the study is evidence that Evista competes with tamoxifen in the marketplace.

***31** 114. With respect to the impact of Eli Lilly's actions on the public at large, Dr. Lewis testified credibly that Eli Lilly's claims pose "a grave public health risk." Tr. at 345 (Lewis). Women at high risk of developing breast cancer may be placed on raloxifene, which has not yet been proven to reduce the risk of breast cancer, instead of on tamoxifen. Indeed, Eli Lilly's own witnesses have conceded that it would be dangerous if physicians relied on inaccurate information about prescription drugs conveyed by sales representatives. Tr. at 246-47 (Nicholson); Tr. at 858-59 (Torres).

II.

CONCLUSIONS OF LAW

1. This Court has jurisdiction over this action alleging violations of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), pursuant to 15 U.S.C. § 1121(a) and 28 U.S.C. §§ 1331 and 1338(a).[FN9]

FN9. While the complaint asserted claims under the New York common law preventing unfair competition and New York General Business Law §§ 349 and 350 preventing deceptive trade practices, those claims are not asserted as a basis for preliminary relief.

2. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

3. A party seeking a preliminary injunction bears the burden in Lanham Act cases, as in all others, of demonstrating (1) that it will suffer irreparable harm if the preliminary injunction is denied and (2) either (a) a likelihood of success on the merits, or (b) serious questions going to the merits to make them a fair ground for litigation and a balance of the equities tipping decidedly in the movant's favor. *See Castrol, Inc. v. Quaker State Corp.,* 977 F.2d 57, 62 (2d Cir.1992). Zeneca and Barr have met this standard.

A. Zeneca and Barr are likely to succeed on the merits

1. *The governing Lanham Act standards*

4. Section 43(a) of the Lanham Act provides a civil remedy to those damaged by one who makes a " false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities ... of his or her or another person's goods, services or commercial activities."15 U.S.C. § 1125(a)(1)(B). Because Section 43(a) is a "remedial statute," it is "broadly construed." *Gordon & Breach Science Publishers S.A. v. American Inst. of Physics,* 859 F.Supp. 1521, 1532 (S.D.N.Y.1994).

5. Courts have consistently held that oral statements by a company's sales representative concerning a product constitute "commercial advertising or promotion" under the Lanham Act. *See, e.g., Abbott Labs. v. Mead Johnson & Co.,* 971 F.2d 6, 10 (7th Cir.1992); *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.,* 984 F.Supp. 768, 772, 796 (S.D.N.Y.1997);

Pfizer, Inc. v. Miles, Inc., 868 F.Supp. 437, 449 (D.Conn.1994).

6. The burden of proving "literal falsity" varies depending on the nature of the challenged claim. When a defendant makes no mention of scientific tests or studies, the plaintiff must affirmatively prove that the statement is false. *See, e.g., Castrol, Inc.*, 977 F.2d at 63;*Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals Co.*, 935 F.Supp. 327, 329 (S.D.N.Y.1996). However, when a defendant's promotion implicitly or explicitly refers to tests or data-a so-called "establishment claim"-a plaintiff can satisfy its burden of proving literal falsity by demonstrating "that such tests are 'not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir.1991) (citation omitted); *see also Castrol, Inc.*, 977 F.2d at 62. This standard of proof applies "[w]hen the ad relies on scientific studies, whether implicitly by making a claim while showing a graph or diagram, or explicitly, by stating, for example, 'that studies show.' " *Glaxo Warner-Lambert OTC G.P.*, 935 F.Supp. at 329;*see also Castrol, Inc.*, 977 F.2d at 63 (when defendant's advertisement "explicitly or implicitly represents that tests or studies prove its product superior, plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited").

***32** 7. A Lanham Act plaintiff seeking to enjoin an establishment claim can meet its burden by showing either (i) "that the tests were not sufficiently reliable to permit [the] conclusion" for which they are cited, or (ii) "that the tests, even if reliable, do not establish the proposition asserted by the defendant" and are thus "simply irrelevant." *Castrol, Inc.*, 977 F.2d at 63. Once a plaintiff has exposed a defendant's tests as irrelevant and/or unreliable, " relief may be granted without reference to the advertisements' impact" on consumers. *Pfizer*, 868 F.Supp. at 452 (quoting *Coca Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir.1982)).

2. *Eli Lilly is making two of the claims in question*

8. As set forth in the Court's Findings of Fact, there is abundant evidence that Eli Lilly representatives are systematically making claims that Evista has been proven to reduce the risk of breast cancer and that Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. This evidence includes (i) the November and December sales representative verbatim scripts, (ii) Eli Lilly's call notes, (iii) the testimony of Eli Lilly's executives, (iv) eyewitness testimony, and (v) Eli Lilly's Richard Day research.

9. Although Eli Lilly and its witnesses effectively conceded that the company's representatives are making the claim that Evista has been proven to reduce the risk of breast cancer, Eli Lilly denied that it is making any improper comparisons to tamoxifen. However, as detailed in the Findings of Fact, the credible evidence shows that Eli Lilly is making the comparability claim versus tamoxifen.

10. The doctors' affidavits submitted by Eli Lilly are not sufficient to undermine the substantial evidence that Eli Lilly's sales representatives have been making the two claims in question. As noted in the first section of this Opinion, the affidavits are necessarily of less weight than the testimony of witnesses who were subject to cross-examination. Moreover, the affidavits themselves are ambiguous as to what Eli Lilly's sales representatives actually said to the doctors. Def.'s Exhs. T-4 through R-5.

11. The affidavits are also less reliable than the other evidence such as oral testimony and contemporaneous business records. The affidavits were made months after the fact of the visits and the visits themselves were quite short. Tr. at 798-99 (Torres).

12. The declarations are also narrowly written and ambiguously worded. Some declarations state that no comparison was made to tamoxifen or Nolvadex. *See, e.g.*, Def.'s Exhs. Z-4 (Decl. of Dr. James William Jackson), A-5 (Decl. of Dr. Frank Davis Jones), N-5 (Decl. of Lawrence Silver), R-5 (Decl. of Dr. John Yacoub). Others state only that no " direct" comparisons were made. *See, e.g.*, Def.'s

Exhs. V-4 (Decl. of Dr. Donald Earle Courts), W-4 (Decl. of Dr. P. Timothy English), F-5 (Decl. of Dr. Francisco Munoz), I-5 (Decl. of Dr. P. Scott Pollack), L-5 (Decl. of Dr. Joanne M. Richards).

***33** 13. Finally, Eli Lilly could have had these doctors testify at the hearing on the preliminary injunction or taken their depositions, even by telephone, to provide the Court with the benefit of cross-examination. Eli Lilly failed to do so, however, and thus the affidavits of the doctors are entitled to less weight.[FN10]

> FN10. Eli Lilly also maintains that the number of call note entries cited by Zeneca with respect to the tamoxifen comparisons are too small to rise to the level of a Lanham Act violation. However, courts have found that statements by sales representatives on a smaller number of occasions than that cited by Zeneca would violate the Lanham Act if those statements were determined to be false. *See, e.g., Pfizer Inc. v. Miles, Inc.,* 868 F.Supp. 437, 460 (D.Conn.1994).

a. *Admissibility of Richard Day survey evidence*

14. Eli Lilly challenged the admissibility of market research conducted on its behalf by Richard Day. Zeneca offered that evidence, among other reasons, to corroborate the call notes and to prove that raloxifene and tamoxifen are competitors in the market.

15. The survey evidence will not be considered by the Court insofar as it is offered to corroborate the call notes. The defendant admitted at oral argument that its sales representatives have been making the " establishment" claim that Evista has been proven to reduce the risk of breast cancer. (Tr. of June 24, 1999 at 69, 74.) That admission, in addition to the call notes, verbatims, and other evidence, make it unnecessary to consider the survey evidence with respect to those claims. In addition, the evidence with respect to the alleged comparative claim that Evista is comparable or superior to tamoxifen for reducing the risk of breast cancer is quite strong based on the evidence detailed in the Findings of Fact, including the call notes and the verbatims. Thus there is no need to consider the survey evidence with respect to those claims. Finally, there is simply insufficient evidence that the defendant has been making the third claim-that Evista is indicated by the FDA for the prevention of breast cancer. The survey evidence in this case does not significantly support this claim by Zeneca and Barr and thus the survey evidence will not be considered with respect to that claim. However, the survey evidence is relevant to the issue of whether raloxifene and tamoxifen are competitors in the marketplace, as discussed below.

3. Eli Lilly's "establishment claim" that Evista has been proven to reduce the risk of breast cancer is *false*

a. *The claim is false*

16. Based on all the evidence adduced, Zeneca and Barr will likely succeed in proving that the MORE trial is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the proposition for which [it was] cited" -namely, that Evista has been proven to reduce the risk of breast cancer. *Procter & Gamble Co. v. Chesebrough-Pond's Inc.,* 747 F.2d 114, 119 (2d Cir.1984).

17. The FDA, as well as numerous other experts in the field of clinical oncology, have reviewed the breast cancer data from the MORE trial and reached the nearly unanimous conclusion that it does not prove that Evista reduces the incidence of breast cancer. The reasons for the unanimity of these organizations are described at length in the Findings of Fact. Most notably, the MORE protocol was not designed to determine whether Evista could be efficacious in reducing the risk of breast cancer. Accordingly, women were not selected for enrollment and once enrolled were not randomized between the raloxifene and placebo arms based on their degree of breast cancer risk. The protocol also did not require annual mammograms or breast physical exams, among other diagnostic

deficiencies. Because of these and other critical flaws, the risk factors may have been imbalanced, the incidence of breast cancer may have been underdiagnosed and the results may yet turn out-as the CORE extension goes forward-to be a "false positive." Given the small number of invasive breast cancers that were diagnosed, a small number of additional invasive breast cancers in the raloxifene arm would have seriously compromised the results of the study.

***34** 18. Courts in this Circuit and elsewhere routinely enjoin claims of proven therapeutic efficacy on the ground that the underlying tests are irrelevant and/or unreliable to support them. *See, e.g., Castrol,* 977 F.2d at 63-64 (finding that tests " which proved faster oiling time, are irrelevant to [the] claim that [the defendant's] oil protects better" and thus the defendant's claim that tests proved that its product provided superior protection to engines was enjoined); *S.C. Johnson & Son, Inc. v. Clorox Co.,* 930 F.Supp. 753, 783 (E.D.N.Y.1996) (enjoining claim that "testing proves Combat SuperBait kills up to 98%" of household roaches because the tests were not reliable and did not measure what was being claimed because testing did not measure effectiveness of product in consumers' homes); *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.,* 906 F.Supp. 178, 182-83 (S.D.N.Y.1995) (enjoining claim that PEPCID AC controls acid "all day," in part because the defendant's studies related to night-time acid relief "[were] not relevant here" and because " [t]here was ... compelling evidence that [the defendant's studies] do not accurately measure acid control"), *aff'd,*100 F.3d 943 (2d Cir.1996); *Pfizer, Inc.,* 868 F.Supp. at 457 (enjoining claim based on a study that lacked a written protocol and scientific controls and noting that there was no discussion of the experimental methodology and controls or lack thereof).

b. *The FDA's findings are probative*

19. Eli Lilly has attempted to exclude and then to minimize the FDA's views on whether Evista has been proven to reduce the risk of breast cancer. FN11 The FDA's views are not determinative and Zeneca and Barr are entitled to a preliminary injunction even without the views of the FDA. Nevertheless, it is appropriate to consider the views of the FDA on the highly regulated issue of drug efficacy.

FN11. The Court found in the first section of this Opinion that the FDA documents concerning Evista are admissible.

20. The FDA is the agency responsible for determining the safety and efficacy of prescription drugs in this country. *See*21 U.S.C. § 393; Tr. at 740-41 (Cummings); Tr. at 1102 (Dere); Lippman Dep. Tr. at 84. Both parties' experts testified that FDA is a recognized authority and has expertise in assessing the results of clinical drug trials. Tr. at 427-29 (Carlson); Tr. at 740 (Cummings); Tr. at 1102 (Dere); Lippman Dep. Tr. at 84. Having reviewed all of the breast cancer data from the MORE trial and having met repeatedly with Eli Lilly's study investigators and scientists, the FDA found that MORE does not and cannot prove that Evista reduces the risk of breast cancer.

21. The fact that the FDA has not approved raloxifene for breast cancer risk reduction does not conclusively demonstrate that the defendant's claim that raloxifene has been proven to reduce the risk of breast cancer is literally false under the Lanham Act because "a Lanham Act plaintiff must prove that the defendant's efficacy claims are literally false, not simply that they fail to meet current federal licensing standards."*Avon Prods., Inc.,* 984 F.Supp. at 797. However, as a recognized expert in evaluating data from clinical trials, the FDA's conclusion as reflected in the Evista label and various FDA documents that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established" is persuasive evidence that Eli Lilly's claims to the contrary are untrue. Other courts have also found the FDA's expert conclusions to be relevant evidence in determining whether a party violated the Lanham Act. *See, e.g., SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.,* 95 Civ. 7011, 95 Civ.

7688, 1996 WL 280810, at *13 (S.D .N.Y. May 24, 1996); *see also American Home Prods. v. Procter & Gamble,* 871 F.Supp. 739, 754 (D.N.J.1994) (expert's conclusion concerning efficacy of analgesic is "bolstered by the FDA's formal findings " concerning the product).

4. Eli Lilly's "establishment claim" that Evista has been proven comparable or superior to tamoxifen is *false*

***35** 22. The cases and arguments set forth above apply with equal force to the second establishment claim-that Evista has been proven comparable or superior to tamoxifen for reducing the risk of breast cancer. Because Evista has not been proven to reduce the risk of breast cancer, it necessarily has not been proven comparable or superior to tamoxifen in that regard.

23. Even if this Court had concluded that the MORE study was relevant and reliable as support for Eli Lilly's first claim, this comparative claim still would have to be enjoined. The experts at trial agreed that it is a fundamental principle of clinical testing that one cannot infer efficacy comparisons between two products when, as here, those products have not been tested against one another in a well-controlled head-to-head clinical study. Eli Lilly's own witnesses have confirmed this principle. Tr. at 180-81, 207-09 (Crenshaw); Tr. at 740 (Cummings); Lippman Dep. Tr. at 34-36. Other federal courts have previously indicated support for this principle. *See, e.g., Thompson Medical Co. v. Ciba-Geigy Corp.,* 643 F.Supp. 1190, 1195 (S.D.N.Y.1986) (noting that the defendant was previously enjoined from making any comparative efficacy claims "unless and until [it] has at least one adequate and well-controlled comparative clinical study which demonstrates such therapeutic advantage or superiority").

24. Eli Lilly has no data-flawed or otherwise-to " establish" the proposition that Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. As Eli Lilly itself recognizes, that is one of the primary objectives of the upcoming STAR trial. Unless and until the STAR trial has been completed and proves that hypothesis, it is a clear violation of the Lanham Act for Eli Lilly to continue making this comparative establishment claim.

5. There is insufficient evidence that Eli Lilly is making the claim that Evista is indicated for the *prevention of breast cancer*

25. The parties agree that Evista is not indicated or approved by the FDA for reduction of the risk of breast cancer. Indeed, Eli Lilly has not even formally applied for such an indication. Zeneca and Barr argue that Eli Lilly is nevertheless promoting Evista as indicated by the FDA for the reduction of the risk of breast cancer, but there is insufficient evidence to support that allegation. As stated in the Court's Findings of Fact, few sales representatives' call notes provide any evidence that such a claim is being made. Moreover, no eyewitnesses testified that they have heard sales representatives making such a claim, no Eli Lilly verbatims instruct sales representatives to make such a claim, and no Eli Lilly witnesses supported the proposition that such a claim was being made. There is insufficient evidence that this claim is being made. Therefore, the Court cannot conclude that Zeneca and Barr are likely to succeed on this claim.

B. Zeneca and Barr have been irreparably harmed

***36** 26. As set forth above, Eli Lilly is making both comparative and non-comparative false establishment claims concerning Evista. As to either type of claim, Zeneca and Barr have demonstrated irreparable harm sufficient to warrant an injunction.

27. Once a plaintiff seeking to enjoin a false comparative claim demonstrates a likelihood of prevailing on the merits, irreparable injury is presumed when the defendant's "literally false ... comparative advertisement ... mentions plaintiff's product by name."*Castrol, Inc.,* 977 F.2d at 62. Moreover, when, as here, "the false or misleading advertising claims create a danger to public health, the presumption of irreparable harm is particularly appropriate."*McNeilab, Inc. v. American Home*

Prods. Corp., 675 F.Supp. 819, 826 (S.D.N.Y.1987), *aff'd*, 848 F.2d 34 (2d Cir.1988). Zeneca and Barr have satisfied the irreparable harm requirement with respect to Eli Lilly's false comparative claim that Evista has been proven comparable or superior to tamoxifen.

28. In the case of non-comparative false claims, the Lanham Act requires "only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising."*Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir.1980); *see also Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir.1994) (noting that while a plaintiff in a Lanham Act case under § 1125(a)" must show more than a subjective belief that it will be damaged [by a false advertising claim], it need not demonstrate that it is in direct competition with the defendant or that it has definitely lost sales because of the defendant's advertisements" and that although injury and causation will not be presumed, "the type and quantity of proof required to show injury and causation has varied from one case to another depending on the particular circumstance") (internal quotation marks and citations omitted); *Coca-Cola Co.*, 690 F.2d at 316 (noting that a plaintiff in a Lanham Act case "must ... offer something more than a mere subjective belief that he is likely to be injured as a result of the false advertising ... he must submit proof which provides a reasonable basis for that belief") (internal citation omitted). To obtain injunctive relief, a Lanham Act plaintiff "need not even point to an actual loss or diversion of sales."*Coca-Cola Co.*, 690 F.2d at 316. Instead the plaintiff must show two things: (i) that the parties are competitors in the relevant market, and (ii) that there is a "logical causal connection between the alleged false advertising and its own sales position."*Johnson & Johnson*, 631 F.2d at 190-91. Zeneca and Barr have demonstrated both.

1. *Zeneca and Barr are competitors of Eli Lilly*

29. Eli Lilly maintains that even if it is making breast cancer reduction claims, it is not in competition with Zeneca or Barr because any Evista prescriptions written as a result of its breast cancer prevention claims are not coming at the expense of Zeneca or Barr; according to Eli Lilly, those prescriptions are likely written primarily for osteoporosis. This argument fails. It is clear that the parties are competitors.

***37** 30. First, by making claims that Evista has been proven or shown to reduce the risk of breast cancer, Eli Lilly has injected Evista into the emerging breast cancer prevention market. Since the only other product in that market is tamoxifen, Evista is clearly positioned by Eli Lilly in competition with tamoxifen, which is manufactured by Zeneca and distributed by Zeneca and Barr. *See Avon Prods.*, 984 F.Supp. at 775-78.

31. The call notes underscore this point. The notes show that Eli Lilly is making blanket and categorical claims of breast cancer risk reduction, not merely claims directed to osteoporosis patients or coupled with osteoporosis claims. *See, e.g.*, Pl.'s Exh. 25, Entry 11/11/98-722809052 ("You can be assured Evista will not increase the risk [of breast cancer] and in every study showed there was a dcrease[d][sic] risk"); Entry 1/18/99-246801181 (" went into ev b. cancer data, told md he could let his women know they will be greater than 55rotected against b. cancer with evista"); Entry 1/26/99-848801056 ("I told him now he can actually say with confidence that Evista actually reduces the incidence of breast cancer"); Entry 2/8/99-240003187 ("point out the fact that there's no 'up-in-the-air' w/ Evista, because we know it reduces breast cancer").

32. These entries are echoed by the testimony of Denice Torres, who, as noted above, testified that in response to unsolicited questions, Eli Lilly representatives can tell physicians that "Evista[ ][has] been demonstrated to reduce the incidence of breast cancer" and that in studies up to three years, Evista reduces the risk of breast cancer by greater than 50 percent. Moreover, Ms. Torres testified that when an Eli Lilly representative states that Evista has been shown to reduce the incidence of breast cancer, the representative need not communicate any drawbacks or limitations, other than that Evista is not indicated for breast cancer risk reduction. Tr. at 217, 225-27, 229, 859-64 (Torres).

33. Second, the call notes show that Eli Lilly representatives are making direct comparisons to tamoxifen and, beyond that, are urging physicians to prescribe Evista instead of tamoxifen, thus squarely putting the two drugs in direct competition for the same prescriptions. *See, e.g.,* Pl.'s Exh. 23, Entry 10/5/98-578403397 ("evista 3 way-wanted to know re breast cancer data-told him the 60-80% reduction-he said what about tamox-said evista's data is better and doesn't increase risk for endometrium either."); Entry 10/12/98-169801604 ("he actually came over to me to talk about golf outing.....wow..... chatted a bit..... said the main thing that he learned was switching patients from tamoxifen to evista... great....."); Entry 11/03/98-244001904 ("he asked right away about BC, went into MORE and compared with Tamoxifen, we agreed that Evista is a much better choice"); Entry 11/16/98-422406095 ("He then wanted to know if I was saying-replace Tamoxifen with Evista. I said well, no FDA approval, but most of the doctors are already doing that, what will you do? He said Tamoxifen rep already came to detail him. I said, so far what you have is study on Tamox vs. placebo and Evista vs. placebo, although you can't really compare, Evista looks better and without the endo effects"); Entry 1/12/99-281202408 ("Evista first line ahead of tamox. for prevention"); Entry 2/17/99-360201058 ("Nolvadex rep had just left.....listened to her give entire tamox detail..... went right in and asked him.....'Dr. Bill, why and where would you ever use Tamox over Evista?"'). These call notes are consistent with Eli Lilly's November 1998 verbatim, which instructed sales representatives to respond to doctors' questions by stating "these results [with respect to Evista's efficacy in reducing the risk of breast cancer] are similar to those for tamoxifen in women at high risk of breast cancer" and to make a favorable comparison to tamoxifen with respect to the safety profile of the drugs. Pl.'s Exh. 15 at EV 2609 327-28.

***38** 34. Third, and as Eli Lilly's Ms. Torres admitted, several internal Eli Lilly documents identify Zeneca as an Eli Lilly competitor. For example, a December 2, 1998 memorandum prepared by Ms. Torres captioned, "Maximizing the Breast Cancer Label Change," refers to an anticipated "competitive response," which Ms. Torres acknowledged was a reference to Zeneca, and goes on to note that "[w]e proactively and assertively position the P.I. change... not our competition."Pl.'s Exh. 16 at EV 2264 401-02; Tr. at 227-28 (Torres). Ms. Torres similarly wrote in a February 18, 1999 memorandum that "[t]here has been disturbing competitive activity involving misrepresentation of our NOV [notice of violation issued to Eli Lilly by FDA]. We are also planning on sharing competitive NOVs (Zeneca, Wyeth) with the Field to assure them we are also monitoring competitive activity ...." Pl.'s Exh. 49.

35. Fourth, Barr is plainly a competitor of Eli Lilly's. Not only does Barr distribute tamoxifen, with which Evista has been positioned to compete, but Barr also manufactures two products-estradiol and estropipate-that compete against Evista in the osteoporosis market. Tr. at 553 (Sawyer). Barr's products in the osteoporosis market give Barr an additional interest in being protected against false promotion of Evista for breast cancer risk reduction because such false promotion is reasonably likely to influence doctors' choices when prescribing a drug for the prevention of osteoporosis.

2. Zeneca and Barr have shown the requisite "causal *connection"*

36. Zeneca and Barr have likewise shown the requisite causal connection between Eli Lilly's conduct and resulting harm to Zeneca and Barr.

37. There is no dispute that tamoxifen is the only drug approved for reduction of the risk of breast cancer. Ms. Anson confirmed that Zeneca is the only manufacturer of tamoxifen in the United States and "for every sale of a tamoxifen tablet in the market, Zeneca is therefore a beneficiary ...." Tr. at 53 (Anson). Barr distributes tamoxifen in its generic form. Thus, if doctors believe Eli Lilly's claim that Evista reduces the risk of breast cancer, Zeneca's and Barr's sales necessarily will be affected; any sale of Evista for breast cancer prevention or risk reduction is a lost sale of Zeneca's and may be a lost sale of Barr's.

38. Although it was not required to do so, Zeneca also presented survey evidence bolstering this point. A market research study conducted by Reed/Haldy/McIntosh, a reputable market research firm in the prescription drug field, concluded that of physicians surveyed, 11 percent of prescriptions for Evista are being written primarily for breast cancer prevention, as opposed to either for osteoporosis or for osteoporosis plus breast cancer, and that 35 percent of physicians have written at least some of their Evista prescriptions primarily for breast cancer prevention. Pl.'s Exhs. 72 & 80; Tr. at 477-79, 487-89 (McIntosh). The study does not prove that these prescriptions are being written because of statements made by Eli Lilly representatives. But since Eli Lilly executives acknowledge that the purpose of detailing these physicians is to persuade them to prescribe Eli Lilly's products, it is reasonable to conclude that at least some of these prescriptions resulted from Eli Lilly's false claims. *See Johnson & Johnson,* 631 F.2d at 190 ("The correct standard is whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales.").

***39** 39. The unique nature of the market in question is also relevant to the issue of whether Zeneca and Barr have demonstrated a causal connection between Eli Lilly's false claims about Evista and injury to Zeneca and Barr. *See Telebrands Corp. v. Wilton Indus., Inc.,* 983 F.Supp. 471, 475 (S.D.N.Y.1997) (irreparable harm will result from false advertising if "the materiality of the false statement coupled with the unique nature of the product" is likely to influence sales). Ms. Anson testified that there are no other drugs anywhere in the world, let alone in the United States, approved to reduce the incidence of breast cancer. Tr. at 47-49 (Anson). She also described this field as a " new marketplace." Tr. at 68-69 (Anson). Therefore, it would be even more difficult to quantify Zeneca or Barr's potential lost sales, particularly since tamoxifen sales cannot be broken down between the prevention and treatment indications. Tr. at 100 (Anson). In *Novo Nordisk A/S v. Becton Dickinson & Co.,* 997 F.Supp. 470, 473 (S.D.N.Y.1998), the court noted that a new entrant into an established market would have "a particularly difficult time proving money damages."Here, there is not only a new product but a new market itself, an even more complex situation.

3. *Zeneca's reputation and goodwill are jeopardized*

40. Injury to Zeneca's goodwill and reputation also supports the showing of irreparable harm. Courts in this Circuit have long held "[t]he likelihood of customer confusion, impairment of plaintiff's reputation and good will and probable diversion of customers, combined with the difficulty of proving actual monetary damages arising from Lanham Act injuries, justifies a presumption of irreparable injury once the violation has been established."*Upjohn Co. v. American Home Prods.,* 598 F.Supp. 550, 555 (S.D.N .Y.1984). Ms. Anson confirmed that there would be a "certain amount of loss of good will or injury to [Zeneca's] reputation from physicians as a result of [Eli Lilly's actions]." Tr. at 68-69 (Anson).

4. Eli Lilly's claim that Zeneca unreasonably delayed *is not meritorious*

41. As a final defense, Eli Lilly asserts that an injunction should not issue because Zeneca purportedly waited nearly nine months to commence this action. The Court rejects this argument.

42. Because of the public's overriding interest in preventing misleading advertising, the defense of laches is "sparingly applied" in Lanham Act cases. *American Home Prods, Corp. v. Johnson & Johnson,* 654 F.Supp. 568, 590-91 (S.D.N.Y.1987). This is particularly true when public health issues are implicated, as they are here. *See American Cyanamid Corp. v. Connaught Labs.,* 800 F.2d 306, 310 (2d Cir.1986) (noting in a trademark infringement case that "the potential consequences of confusion over medicinal products may be far more dire than of confusion over ordinary consumer products"); *Conopco, Inc. v. Campbell Soup Co.,* 95 F.3d 187, 194 (2d Cir.1996) (noting in a Lanham

Act case that "the public's interest is especially significant when health and safety concerns are implicated" and that "public health and safety concerns may well overwhelm other considerations in the application of laches").

***40** 43. Here, there is no question that Zeneca has been vigilant in asserting its rights. Zeneca could not have filed this action before early November even if it had had sufficient evidence of Eli Lilly's misconduct by then. The FDA did not allow Zeneca to market tamoxifen for breast cancer risk reduction until late October 1998. It was not until early November, when Zeneca's marketing efforts began in earnest, that Zeneca and Eli Lilly became " competitors" in the breast cancer risk reduction market. Only then did Zeneca first have standing to sue under the Lanham Act. *See Johnson & Johnson,* 631 F.2d at 189 (only competitors, either direct or indirect, have standing to sue for Lanham Act violations).

44. Moreover, when Zeneca first received anecdotal evidence of Eli Lilly's misconduct last May, the Chief Executive Officer of Zeneca wrote to Eli Lilly's President complaining about what the sales representatives were saying about Evista. Pl.'s Exh. 1. Eli Lilly's President assured Zeneca at that time not only that Eli Lilly representatives would not make breast cancer prevention claims, but that any representatives who did so would be punished. Pl.'s Exh. 2. Zeneca cannot be faulted for relying on the word of Eli Lilly's president. Moreover, as Ms. Anson testified, the evidence of false claims began to escalate noticeably in November, after Zeneca was approved for breast cancer risk reduction, and in December, after the Evista label change. Tr. at 63-64 (Anson). Most of Eli Lilly's false statements date from late 1998, when, as the evidence shows, Eli Lilly representatives began to implement the revised November and December detailing scripts. Ms. Anson also explained that Zeneca acted on its suspicions and altered questions in its survey research to try to confirm the anecdotal proof it had gathered. Tr. at 64-65 (Anson). Zeneca obtained the results of the Reed/Haldy/McIntosh survey in January, and then promptly contacted its attorneys and filed this action shortly thereafter in February. Tr. at 65-66, 68 (Anson).*See Warner Lambert v. McCrory's,* 718 F.Supp. 389, 394-95 (D.N.J.1989) ("good faith preparation for litigation," including " commission [of] a study of possible consumer confusion,""should not be used to subsequently bar plaintiff from obtaining injunctive relief"). Thus, Zeneca did not delay unreasonably in bringing the current lawsuit.

45. The cases offered by Eli Lilly on the issue of delay confirm that delay in filing suit is not a bar to injunctive relief when, as here, "the plaintiff was making good faith efforts to investigate" the basis for its claims. *Krueger Int'l, Inc. v. Nightingale Inc.,* 915 F.Supp. 595, 613 (S.D.N.Y.1996). Unlike a typical false advertising case, where there is no dispute about what a defendant is claiming in television or radio commercials or in print advertisements, Zeneca faced the formidable hurdle of proving what a competitor's sales representatives were saying during in-person detail visits with doctors-a hurdle Zeneca has now cleared. In short, based on both the law and the facts, Zeneca did not unreasonably delay in bringing this action.

***41** 46. Moreover, there is no question that Barr did not unreasonably delay in this case. Barr first read in a trade publication that Eli Lilly was making claims that Evista reduces the risk of breast cancer in January 1999. It then learned in February 1999 that Zeneca had filed suit against Eli Lilly. Barr moved in March 1999 to intervene in this action. Tr. at 551-52 (Sawyer). Under these circumstances, there is no credible argument that Barr's claims against Eli Lilly are precluded by the doctrine of laches.

C. The equities weigh decisively in favor of an injunction

47. Since Zeneca and Barr have shown a strong likelihood of prevailing on the merits, it is unnecessary to reach the balance of equities. However, a preliminary injunction would be warranted under this standard also. Zeneca and Barr have plainly raised sufficiently serious questions going to the merits to make them fair ground for litigation. Equally clear, the balance of equities in this case tips decidedly in favor of granting an

injunction.

48. As a result of more than two decades of research and testing by Zeneca as well as the investment of millions of dollars in research and development, tamoxifen is the only drug approved in the United States for the reduction of the risk of breast cancer. Tr. at 47-48, 68 (Anson). The evidence demonstrates that Eli Lilly's conduct threatens to erode the sales, goodwill, and physician and consumer confidence that Zeneca has developed over the years.

49. In contrast to the serious injury that will continue to befall Zeneca and Barr in the absence of an injunction, the comparative harm to Eli Lilly from an injunction is not great. Eli Lilly will merely be relegated to promoting Evista for its only approved use, prevention of osteoporosis. Eli Lilly can "assert no equitable interest in the perpetuation of an advertising campaign that is literally false." *Castrol, Inc. v. Pennzoil Co.*, 799 F.Supp. 424, 440 (D.N.J.1992), *aff'd*,987 F.2d 939 (3d Cir.1993). Eli Lilly can continue, without violating the Lanham Act, to disseminate truthful information about Evista , including the results of the MORE study, and the existence of ongoing studies, so long as this information is in fact truthful.

50. The public interest also requires that an injunction issue. When an allegedly false claim pertains to a prescription drug, the public interest in receiving truthful information is particularly acute. Dr. Jerry Lewis testified that by telling physicians that Evista has been proven to reduce the risk of breast cancer Eli Lilly has created a "grave public health risk." Tr. at 345-46 (Lewis). And Eli Lilly's own witnesses have confirmed the obvious: it could be dangerous if a physician prescribes a drug erroneously believing that the drug could prevent cancer. Tr. at 247 (Nicholson). The evidence shows that doctors are prescribing Evista for the reduction of the risk of breast cancer. Although off-label prescribing-prescribing drugs for uses for which they are not indicated by the FDA-is not uncommon among physicians, Ans. ¶ 1, it would be dangerous if physicians off-label prescribed Evista for breast cancer prevention based on false information about whether Evista has been proven to reduce the risk of breast cancer. It is important to the public interest and to the patients involved that truthful information be provided.

D. The relief granted by the Court

***42** 51. "[C]ourts retain a great deal of flexibility when fashioning preliminary relief ...."*Abbott Labs.*, 971 F.2d at 23. The Court of Appeals for the Second Circuit has held that "the essence of equity jurisdiction has been the power to grant relief no broader than necessary to cure the effects of the harm caused by the violation."*Forschner Group, Inc. v. Arrow Trading Co.*, 124 F.3d 402, 406 (2d Cir.1997). Thus although "[a] district court has a wide discretion in framing an injunction in terms it deems reasonable to prevent wrongful conduct," *Forschner Group, Inc.*, 14 F.3d at 406 (internal quotation marks and citation omitted), the injunction framed by the district court must be " narrowly tailored to fit specific legal violations ... [and] should not impose unnecessary burdens on lawful activity."*Waldman Publ. Corp. v. Landoll, Inc.*, 43 F.3d 775, 785 (2d Cir.1994). Finally, a court's order of preliminary injunctive relief should be explicit and clear so that "those who must obey [it] will know what the court intends to forbid."*EFS Marketing, Inc. v. Russ Berrie & Co.*, 76 F.3d 487, 493 (2d Cir.1996) (internal citations and quotation marks omitted).

52. Applying the above standards to the Court's Findings of Fact and Conclusions of Law, the Court hereby preliminarily enjoins Eli Lilly from stating in its advertising or promotional activities that (i) Evista has been proven, shown, or demonstrated to reduce the risk of breast cancer, or that (ii) Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. The Court will not enjoin Eli Lilly from stating that Evista has been approved by the FDA for the reduction of the risk of breast cancer because, although the claim is plainly false, there is insufficient evidence for the Court to conclude at this stage that Eli Lilly has been making such a claim and therefore Zeneca and Barr have failed to establish that they are entitled to a preliminary injunction on that claim.

53. The Court will not order the corrective advertising sought by Zeneca and Barr, although the Court recognizes that it has the discretion to order such relief. *See, e.g., Linotype Co. v. Varityper, Inc.*, 89 Civ. 4747, 1989 WL 94338, at *3 (S.D.N.Y. Aug. 4, 1989) (ordering corrective advertising, in non-establishment case, "to counteract the false impression that may have been placed by the [defendant's] ad in consumer's minds") (citation omitted). Such relief would be unnecessarily broad. The false information that Eli Lilly sales representatives have disseminated to physicians concerning raloxifene will be corrected by the revised detailing the sales representatives do after completing the training program ordered below.

54. The Court hereby orders defendant Eli Lilly to design and implement a training program for those Eli Lilly sales representatives who are responsible for detailing physicians about Evista, as well as oncology sales representatives and any other sales representatives who may reasonably be expected to encounter questions from physicians about Evista and its efficacy in reducing the risk of breast cancer. The training program should be designed to ensure that Eli Lilly's sales representatives are made aware of and adhere to this Court's decision and order and do not make claims in the field that tamoxifen has been proven to reduce the risk of breast cancer or that it is comparable or superior to tamoxifen for the reduction of the risk of breast cancer. The training program should also explicitly inform sales representatives about the MORE data, the ongoing CORE and STAR trials, and the package insert statement that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established."*See Pfizer,* 808 F.Supp. at 461 (in addition to granting a preliminary injunction, Court ordered Pfizer to hold training sessions with its sales representatives to make them aware of the Court's finding that Pfizer had violated the Lanham Act by making false establishment claims about Pfizer's drug); *Valu Eng'g, Inc. v. Nolu Plastics, Inc.*, 732 F.Supp. 1024, 1026-27 (N.D.Cal.1990) (ordering defendant to send a letter to its sales representatives instructing them to stop making false advertising claims).

Conclusion

***43** At the present time, the evidence before the Court demonstrates that it is literally false for Eli Lilly to claim that raloxifene has been proven to reduce the risk of breast cancer or that raloxifene is comparable or superior to tamoxifen for that purpose. Such statements are false because, although the data from the MORE trial are promising, given the deficiencies in that trial, the MORE data are insufficient to support such claims, thus requiring further study of raloxifene before such claims can be made.

For the reasons explained above, the Court grants the motion of Zeneca and Barr for a preliminary injunction with respect to the establishment and comparative establishment claims and denies it with respect to the indication claim. A separate Order will be issued containing the Preliminary Injunction set out above.

SO ORDERED.

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